K100576

510(K) Summary

ICU MEDICAL INC.

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Tracy S. Best, Sr. Regulatory Affairs Specialist

Preparation Date: 05/28/2010

DEC 17 2010

Summary of Safety and Effectiveness for the:

Trade Name:	High Pressure Sets – 400 psi	
Common Name:	High Pressure Infusion Devices	
Classification Name:	Primary	21 CFR 880.5440, Class II Device, 80FPA
	Secondary	21 CFR 870.4290, Class II Device, 74DTL

Legally Marketed Predicate Devices for Substantial Equivalence:

*K061285 – Smart Site Valve Sets – Cardinal Health, Inc.
*K941978 – High Pressure Tubing, – Abbott Labs (submission acquired by ICU Medical Inc.)
*K963749 – High Pressure Injection Line, Maxxim Medical, Inc.

Rationale for SE:

The ICU Medical High Pressure Sets are substantially equivalent to the predicate devices that offer needleless connectivity and international luer compatibility. The use of ICU's legacy line of connectors is complimentary to these pre-assembled, individually packaged, and pre-sterilized high pressure sets. High pressure sets are used in cardiovascular procedures where contrast media is injected using control syringes or power injectors is common among all devices, which are safe for use up to 400 psi. These features are substantially equivalent to the predicate devices in that they also utilize male luers; female luers or locking luer connectors. Components of the devices are made from materials that are substantially equivalent to the predicate devices listed above and this submission includes comprehensive biocompatibility testing for all device materials included in this submission. Additionally, all devices have a proven and invaluable history in the medical device market.

Description of Submitted Device:

The High Pressure Sets are a group of luer compatible connection devices that aid in the prevention of needlesticks and offer ease of use in the environment for the healthcare professional. The use of the CLAVE®; MicroCLAVE™; Y-CLAVE™; and CLC2000™ is a natural fit with the high pressure sets. Testing included with this submission, validates the 400 psi claim with these unique connectors. The functional technology of the high pressure set has not changed but is augmented by the addition of the ICU connectors. The devices are sterilized to ensure a 10^{-6} SAL and they have been tested under the ISO 10993-1:2003 – *Biological evaluation of medical devices – Part 1: Evaluation and testing* and the results from these tests were found to be acceptable and are enclosed in this submission.

Non-Clinical Testing:

Testing (simulated use) has been conducted according to the product specification and that testing demonstrates that the device is safe and effective by meeting predefined criteria. Test data is part of this submission as evidence.

Intended Uses of the ICU Medical High Pressure Sets:

The high pressure extension set is a device used as conduit tubing to deliver fluids from an electronic or manual injector and may also be used as connector tubing to provide a sterile fluid pathway between two devices. Fluids may include: Contrast media (at 10mL/second) or other medications, and blood or blood products as the physician may prescribe. The fluids are administered through a cannula or catheter placed in a vein or artery. The incorporation of ICU proprietary connectors such as the CLAVE; MicroCLAVE; Y-CLAVE; and CLC2000 with the extension sets, allows for needleless connectivity to other devices via universal luer connection. The maximum pressure is 400 psi and other ancillary devices must also be rated for pressure up to 400 psi.

Technological Characteristics and Substantial Equivalence Table:

Component	ICU Medical High Pressure Sets	Cardinal Health Smart Site Valve Sets	Abbott Labs (submission acquired by ICU Medical)	Maxxim Medical High Pressure Injection Line
Materials	Tubing-PVC Luers – PC, PVC & proprietary needleless devices	Tubing – PVC Luers – PC & proprietary needleless devices	Tubing – PVC Luers – PC & PVC	Tubing – PVC Luers – Plastic (PC assumed)
Functional use	High pressure infusion	High pressure infusion	High pressure infusion	High pressure infusion
Sterilization Method	Gamma	EtO	EtO and Gamma	Unknown
Packaging	Peel pouch	Peel pouch	Peel pouch	Peel pouch
510(k) Approval	This submission	K061285	K941978	K963749

Safety and Performance:

ICU Medical's commitment to quality and the high pressure sets that we currently make with the acquired K941978 submission are part of this submission. The use of these devices at pressures up to 400 psi has been tested and thoroughly proven to be safe and effective when coupled with the CLAVE; MicroCLAVE; Y-CLAVE; and COC2000. These high pressure sets are individually packaged and pre-sterilized in a peel type pouch. Devices are obtainable at custom lengths, according to facility needs and physician preference, including the type of luer ends used. Additionally, ICU Medical performs analysis and design verification testing based on predetermined criteria, which is presented in the Performance Specifications in this submission. All testing meets these performance criteria as defined for the high-pressure. The design of the sets, including the proprietary needleless connectors allow luer connections as defined by ISO 594-1 and ISO 594-2 which is considered to be an industry standard.

Conclusion:

The materials, performance, and operational features of the submitted devices and the predicate devices are substantially equivalent to one another and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Tracy Best
Senior Regulatory Affairs Specialist
ICU Medical, Incorporated
4455 Atherton Drive
Salt Lake City, Utah 84123

DEC 17 2010

Re: K100576
Trade/Device Name: High Pressure Sets – 400 psi
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 30, 2010
Received: November 5, 2010

Dear Mr. Best:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

DEC 17 2010

510(k) Number (if known): K100576

Device Name: High Pressure Sets – 400 psi

Indications for Use:

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Prescription Use __XX__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 12/17/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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